

510(k) Summary

Date of Summary: June 27, 2013

Applicant: Caldera Medical, Inc.
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SEP 23 2013

Contact: Vicki Gail
QA/RA and Operations Manager
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Trade Name: Desara®
Desara® Blue
Device Class: Class II
Product Code: OTN
C.F.R Section: 21 CFR 878.3300
Common name: Surgical Mesh, Gynecologic, For Stress Urinary
Incontinence, Female
Classification Panel: Obstetrics/Gynecology Panel
Predicate Device: Desara® Mesh , K112609

Description of Device:

Desara® and Desara® Blue devices are sterile, single-use mid-urethral slings used to provide support in the pelvic region to treat stress urinary or mixed incontinence. The devices are manufactured out of monofilament polypropylene yarn, which is knitted into a mesh. The devices have integral sleeves, tips and sutures to assist the surgeon in placement of the mesh, which are removed after placement of the device.

Desara® and Desara® Blue are designed to work with Caldera Medical's reusable introducers, which utilize a Universal Connection System offering surgeons the flexibility to choose their preferred surgical approach.

Intended Use of Device:

Desara® and Desara® Blue devices are intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Summary of Technological Characteristics

Desara[®] and Desara[®] Blue devices submitted herein contain changes in polypropylene mesh resin, a decrease to the size of the junction tip and an optional design which contains blue colorant. Desara[®] and Desara[®] Blue are the same shape and size, utilize the same mesh knit and limited contact raw materials as the predicate device, Desara[®] Mesh (#K112609).

Desara[®] and Desara[®] Blue have a more specific intended use than that of the predicate device, Desara[®] Mesh (#K112609) and the same fundamental scientific technology.

Performance Summary

Desara[®] and Desara[®] Blue submitted herein are comprised of the same mesh resin as the reference device, Ascend[®] Blue, (#K101462), also a product of Caldera Medical. In accordance with the *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh*, the following mesh characteristics were assessed: mesh thickness, mesh knit characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels.

Desara[®] Mesh (#K112609) and Ascend[®] Blue, (#K101462) were used as a reference for Desara[®] and Desara[®] Blue devices for biocompatibility since they are comprised of the same materials. Desara[®] Mesh (#K112609) and Ascend[®] Blue, (#K101462) have passed all biocompatibility testing as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product)*, 3. *Biocompatibility* and *FDA Draft Guidance Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing"*, dated April 23, 2013.

Results of both mechanical bench and validation testing demonstrate equivalent device function based upon its intended use to the predicate device, Desara[®] Mesh, (#K112609).

Testing documentation from Desara[®] Mesh (#K112609) and Ascend[®] Blue, (#K101462) were used to support the aging, shelf life, transportation and sterilization of Desara[®] and Desara[®] Blue submitted herein in, was performed in accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA, FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product)*, 4. *Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* as the devices are comprised of the same or similar materials, and utilized the same packaging, manufacturing and sterilization processes as that of Desara[®] Mesh (#K112609).

Summary of Substantial Equivalence

The conclusions drawn from the non-clinical and clinical tests demonstrate that Desara[®] and Desara[®] Blue submitted herein are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 23, 2013

Caldera Medical, Inc.
% Vicki Gail
QA/RA and Operations Manager
5171 Clareton Drive
Agoura Hills, CA 91301

Re: K132069
Trade/Device Name: Desara and Desara Blue
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OTN
Dated: June 27, 2013
Received: July 3, 2013

Dear Vicki Gail,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132069

Device Name: Desara®
Desara® Blue

Indications for Use:

Desara® and Desara® Blue are intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use ☒
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

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PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S

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